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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,937	08/08/2006	Michael Ausborn	33566-US-PCT	1841

1095 7590 03/15/2010

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
PACKARD, BENJAMIN J	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
03/15/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/581,937	AUSBORN ET AL.	
	Examiner	Art Unit	
	Benjamin Packard	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,14-16 and 18* is/are pending in the application.

4a) Of the above claim(s) *15,16 and 18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1pg (6/7/06), 4pgs (10/01/08)*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Election/Restrictions

Applicant's election with traverse of Group 1, claims 1-7 and 14 in the reply filed on 11/25/09 is acknowledged. The traversal is on the ground(s) that the search for the device/method claims in the same application would not pose a serious burden under MPEP § 803 and § 808.02 because of the commonality of the dominant elements between Groups 1, 2, and 4. This is not found persuasive because this case is a national stage entry of a WIPO application, thus restriction is not based on US practice, but under the Unity of Invention standard under PCT Rules 13.1 and 13.2. Where Applicants have not presented arguments with regards to the common technical feature providing a contribution over the prior art, the restriction remains proper.

The requirement is still deemed proper and is therefore made FINAL.

Claims 15, 16, and 18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 6, and 7 are rejected under 35 U.S.C. 102(a) as being anticipated by Dadsetan et al (Journal of Controlled release, 93 (2003) pp 259-270).

Dadsetan et al teaches poly(ethylene carboxylate) (PEC) film applied to stainless steel wire mesh cages (pg 260 sections 2.1 Materials and 2.2 Cage implantation).

Claims 1-5 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Acemoglu et al (WO 1995/006077).

Acemoglu et al discloses microparticles of PEC encapsulating rhIL-6[1] (pg 44 Example 27). The poly(ethylene carboxylate) is disclosed to have the formula -(-C(O)-O-CH2-CH2-O-)- having an ethylene carbonate content of 70 to 100 Mol%, having an intrinsic viscosity of 0.4 to 4.0 dl/g measure in chloroform at 20^{O}C, and having a glass transition temperature of from 15-50^{O}C and shows in vivo and in vitro degredation by surface erosion which is governed by a non-hydrolytic mechanism (pg 11 3rd to 4th paragraphs and claim 1).

Note, while the instant specification states “The medical device may be chosen form catheters, guide wires…”, such a recitation is not limiting given the use of the open ended transition term “may”. Thus, when interpreting the term “device” of the claims, Examiner interprets the term broadly to include microparticles of the biodegradable polymer where the claim recites a device comprises the biodegradable polymer and the surface thereof is “coated” with the polymer.

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[1] Makishima et al (Interleukin-6 is an antiproliferative to a mouse hybridoma cell line and promotive for its antibody productivity, Cytotechnology 10 (1992) pp15-23) verifies that rhIL-6, i.e. IL-6 or interluken-6, is

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Claims 1-7 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dadsetan et al (Journal of Controlled release, 93 (2003) pp 259-270) in view of Acemoglu et al (WO 1995/006077).

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an anti-proliferative (pg 18, last sentence of 2nd full paragraph which states "… 2E3 cells were sensitive to the antiproliferative effect of IL-6 …").

Dadsetan et al is discussed above but does not disclose an additional pharmaceutically active agent.

Acemoglu et al is discussed above but does not tech application to a stent.

It would be obvious to one of ordinary skill in the art when coating a stent, as disclosed on the primary reference, to include a pharmaceutically active agent in the coating in order to provide the expected antiproliferative effect of the active agent as it is released from the coating, as provided by the secondary reference.

Claims 1-7 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roorda (US Pregrant Pub 2001/0007083).

Roorda teaches it was known in the art to apply biodegradable coatings to stents with active agents contained therein (paragraphs 32 and 47). Biosoluble or bio-degradable polymeric materials are disclosed to include polycarbonates and polyethylenes (paragraph 34). The biodegradable material, coupled with the therapeutic substance affects the release rate of the substances (paragraph 40). Particles with biodegrable properties include poly(ethylene carbonates) (paragraph 41).

Roorda, while disclosing coating stents with biodegradable materials, does not specifically disclose a preferred working embodiment with poly(ethylene carbonate) particles coated on a stent.

It would have been obvious to one of ordinary skill in the art when fabricating the drug laden coated stent of Roorda to pick and choose from among the disclosed drug

carrying materials to select a biodegradable materials, such as poly(ethylene carbonate), given it would be selected for its disclosed function.

Claims 1-7 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawaguchi et al (Chem Pharm Bull 31(4) (1983)1400-1403).

Kawaguchi et al teaches sutures and surgical implants were well known to be coated by biodegrable polymers for specialized controlled release formulation of drugs (pg 1400 first paragraph). Further, Kawaguchi et al teaches poly(ethylene carbonate) has favorable biodegradation rates in vivo (pg 1401, Results and Discussion).

Kawaguchi et al does not disclose a poly(ethylene carbonate) drug loaded coated stent as a specifically disclosed embodiment.

It would have been obvious to one of ordinary skill in the art, when reading Kawaguchi et al to apply the poly(ethylene carbonate) coating to sutures and surgical implants, given its favorable properties for such a use. Further, the term surgical implant is interpreted to include stents, given stent are surgically implanted within a patient.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Packard whose telephone number is 571-270-3440. The examiner can normally be reached on M-F 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Benjamin Packard/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612